

**LABORATORY QUALITY MANUAL**  
**Protocol for the Certification of Laboratories Performing Tuning Fork Certification Testing**  
**Proc. #9-215, Rev. 8 [August 2013]**

Facility Name: \_\_\_\_\_ Lab ID: \_\_\_\_\_

Assessor Name: \_\_\_\_\_ Review Date: \_\_\_\_\_ On-Site Inspection Date: \_\_\_\_\_

	Relevant Aspect of Protocol	Reference	Y	N	NA	Comments
1.	Company name, address and contact information	III.B.1				
2.	Statements affirming the laboratory's commitments to quality assurance and data integrity.	III.B.2				
3.	List of personnel and qualifications	III.B.3				
4.	Log of printed names, handwritten initials and signatures of all laboratory personnel authorized to perform tuning fork testing, data review, and certificate notarization.	III.B.4				
5.	List of all testing equipment—including manufacturer, model, and serial number—used in the certification procedure.	III.B.5				
6.	Information describing the accuracy, range and reproducibility for each instrument and item of support equipment used for the testing and certification of tuning forks.	III.B.6				
7.	Corrective Action Policy for response when instrumentation fails to meet fitness for use acceptance criteria.	III.B.7				
8.	Schedules for instrument calibration and maintenance including requirements for documenting calibration and maintenance.	III.B.8				
9.	Description of circumstances that would require recertification of reference tuning forks (trauma, damage or change in performance).	III.B.9				
10.	Processes and procedures for ensuring traceability of measurements to nationally recognized standards.	III.B.10				
<b>Description of Procedures being performed, equipment being used, calculations, and examples, adjustments (if any), and references. This information may be included in the Quality Manual or may be a separate Standard Operating Procedure (SOP). At a minimum, the information shall include:</b>						
11.	Sample receiving and tracking procedures.	III.B.11.a				
12.	Sample Rejection Policy describing the circumstances under which a tuning fork would not be accepted for testing.	III.B.11.b				

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13.	Procedures for labeling and disposition of rejected tuning forks.	III.B.11.c				
14.	Instructions for instrument setup, fitness for use testing and documentation, and acceptance criteria.	III.B.11.d				
	<b>The procedure for testing tuning forks submitted by law enforcement agencies for certification and documenting test results:</b>					
15.	Reference tuning forks tested prior to beginning testing and at the conclusion of each sample set	III.B.11.e.i				
16.	Frequency of oscillation of each reference tuning fork shall be within $\pm 0.5\%$ of that specified by the manufacturer or the most recent independent certification	III.B.11.e.ii				
17.	Temperature of the test environment not less than 20°C and not greater than 30°C	III.B.11.e.iii				
18.	At least 2 frequency observations recorded and averaged for the calculation of MPH	III.B.11.e.iv				
19.	Each page of test documentation dated and initialed by the analyst	III.B.11.e.v				
	<b>Review and reporting of test data and calculations:</b>					
20.	Process for reviewing and reporting test data and calculations	III.B.11.f				
21.	Data review documented with date and initials of reviewer	III.B.11.f.i				
22.	Final reports notarized	III.B.11.f.ii				
23.	Processes for customer notification as well as labeling and disposition of tuning forks that fail the certification testing	III.B.11.g				
<b>Technician Training: Description of the complete training process and supporting documentation</b>						
24.	Training goals and expected results	III.B.12.a				
25.	Learning objectives and expectations upon completion of training	III.B.12.b				
26.	Learning methods and/or activities	III.B.12.c				
27.	Documentation of training	III.B.12.d				
28.	Training effectiveness criteria	III.B.12.e				

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29.	Evaluation of training—assessment of documentation against criteria	III.B.12.f				
<b>Demonstration of Capability—a procedure for establishing technician competence in testing and establishes acceptance criteria for the evaluation of analyst capability:</b>						
30.	Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork	III.B.13.a.i				
31.	Each technician shall calculate the mean and standard deviation of each data set	III.B.13.a.ii				
32.	The frequency of oscillation of each reference tuning fork shall be within $\pm 0.5\%$ of that specified by the manufacturer or the most recent independent certification	III.B.13.b				
<b>Record Retention Policy</b>						
33.	Maintenance logs retained for a minimum of three (3) years	III.B.14.a.i				
34.	Calibration records retained for a minimum of three (3) years	III.B.14.a.ii				
35.	Sample observation records retained for a minimum of three (3) years	III.B.14.a.iii				
36.	Training records and Demonstration of Capability retained for a minimum of three (3) years	III.B.14.a.iv				
<b>Documentation practices</b>						
37.	All handwritten data shall be recorded in ink	III.B.14.b.i				
38.	Changes to laboratory records shall be made with a single strike-out line leaving the original entry visible	III.B.14.b.ii				
39.	Changes shall be documented with date and initials of person making the correction	III.B.14.b.iii				
40.	Describe procedures for ensuring the security of electronic records	III.B.14.c				

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<b>A sample copy of a certificate issued to customers showing the following</b>						
41.	Serial number or other unique identifier of the tuning fork	III.B.15.a				
42.	The frequency at which the tuning fork was found to oscillate and the corresponding MPH (miles per hour)	III.B.15.b				
43.	The designation of the radar frequency band within which the tuning fork is to be used	III.B.15.c				
44.	Date of certification testing	III.B.15.d				
45.	Signature of the analyst who performed the testing	III.B.15.e				
46.	Date, seal and signature of notarization	III.B.15.f				
47.	Any additional information required by court systems of the jurisdictions in which laboratory's clients are located	III.B.15.g				
48.	Change sheet to allow historic reconstruction of changes to the Quality Manual	III.B.16				
49.	Annual review and signature sheet	III.B.17				